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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/594,941	03/13/2008	Roberta Martinetti	BUG5-41416	5670		
86378	7590	01/19/2011	EXAMINER			
Pearne & Gordon LLP			STEWART, JASON-DENNIS NEILKEN			
1801 East 9th Street			ART UNIT			
Suite 1200			PAPER NUMBER			
Cleveland, OH 44114-3108			3738			
NOTIFICATION DATE		DELIVERY MODE				
01/19/2011		ELECTRONIC				

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patdocket@pearne.com  
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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/594,941	MARTINETTI ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	JASON-DENNIS STEWART	3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 08 November 2010.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

The following is a Final Office action in response to communications received on 11/08/10. Claims 1-10 have been amended. Claims 1-10 are currently pending and addressed below.

### ***Response to Amendment***

The amendments to the specification are sufficient to overcome the 35 U.S.C. 112, 2nd paragraph rejections of the previous Office action.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
2. Claims 1, 3, and 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso 5,741,215 in view of Taboas et al. 2003/0006534 in view of Cima et al. 5,490,962.

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3. D'Urso teaches a method of forming a prosthetic implant (abstract) that may be made of ceramics, or more specifically, hydroxyapatite (col. 5, ll. 29-33) (Claims 6, 9). D'Urso teaches using a CT scan of a patient to obtain a model showing the defect to be reconstructed (abstract) (claim 1), using prototyping to create a model of the defect (col. 4, ll. 26-33), forming the model, and constructing a mould or mould surface (negative mould) (col. 5, ll. 9-16). However, D'Urso does not teach the controlled porosity of the ceramic implant or a mechanical finishing step.

Taboas teaches a method of creating ceramic scaffolds that can support drug delivery (paragraph 7) (Claim 10) having direct or indirect solid free form (SFF) fabrication. The scaffolds may have an interconnected porosity with pore dimensions .1-.125 microns and 125-2500 microns range (paragraphs 22-27) (Claim 1). Taboas also teaches manually processing a semi-finished product to obtain a final product (paragraph 12) (Claim 1).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of D'Urso with the ceramic scaffolds taught by Taboas in order to produce structures that mimic natural tissue properties as taught by Taboas (paragraph 7).

D'Urso in view of Taboas teaches the invention as claimed and as discussed above, however, D'Urso in view of Taboas does not teach a biomodal distribution of pore sizes in the medical implant.

Cima teaches making medical implants suitable for allowing bone regeneration (Claim 10) that have large (200-500 micron) and small (1-10 micron) pores (col. 13, l. 50 - col. 14, l. 19) (Figs. 2A-2C).

It would have been obvious to modify the method of fabrication of D'Urso in view of Taboas with the pore distribution of Cima in order to construct a porous matrix for bone regeneration as taught by Cima (col. 13, ll. 51-52).

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over D'Urso 5,741,215 in view of Taboas et al. 2003/0006534 in view of Cima et al. 5,490,962, as applied to claim 1 above, and further in view of Cummings et al. 2004/0152034.

5. D'Urso in view of Taboas in view of Cima teaches the invention as claimed and as discussed above. However, D'Urso in view of Taboas in view of Cima does not teach that the manual finishing is done with a diamond mill cutter.

Cummings teaches finishing a ceramic implant with a diamond milling cutter (paragraph 255).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of D'Urso in view of Taboas in view of Cima by using a diamond milling cutter as taught by Cummings because such a device is commonly known and used in the art for such a task.

***Allowable Subject Matter***

6. Claim 4 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

7. Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

8. The Applicant argues that D'Urso does not teach using a negative mould of a patient's bone defect. The Examiner respectfully disagrees. D'Urso teaches the use of a mould of "mould surface" (col. 5, ll. 1-15), which is what a negative mould is, to create an implant. It is the interpretation of the Examiner that D'Urso at least suggests a negative mould since the D'Urso has distinguished between a mould (positive mould) and a "mould surface" (negative mould).

9. The Applicant also argues that D'Urso does not teach a semi-finished product that is slightly larger than the dimensions of the defect that is later processed to create a finished product. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

10. D'Urso teaches that the model may include a region adjacent to the region of pathology to be modeled (col. 5, l. 66 – col. 6. l. 3). This is used as “a template for accurate fit of a prosthesis”. This suggests a border around the model. Also, Toboas teaches “finishing” methods that lead to a final product (paragraph 12).

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JASON-DENNIS STEWART whose telephone number is (571)270-3080. The examiner can normally be reached on M-F (alt Fridays off) 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571)272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jason-Dennis Stewart/  
Examiner, Art Unit 3738

/DAVID ISABELLA/  
Supervisory Patent Examiner, Art Unit 3774